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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,825	01/15/2002	Rodrigo F. Chaqui	66043	8611
45323	7590	02/09/2005	EXAMINER	
NATIONAL INSTITUTES OF HEALTH C/O VENABLE LLP P. O. BOX 34385 WASHINGTON, DC 20043-9998			DAVIS, MINH TAM B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/743,825	Applicant(s) CHAQUI ET AL.	
	Examiner MINH-TAM DAVIS	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/05/04; 11/17/04.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-8 and 10-40 is/are pending in the application.
4a) Of the above claim(s) 6-8 and 13-16 is/are withdrawn from consideration.
5) ☒ Claim(s) 2,3,5,17,18 and 27-29 is/are allowed.
6) ☒ Claim(s) 10-12,19-26 and 30-40 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/08/02</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant adds new claims 20-40, which are not new matter and are related to claims 2-3, 5, 10-12, 17-19.

Accordingly, claims 2-3, 5, 10-12, 17-40, SEQ ID No: 1 and fragments thereof of SEQ ID NO: 7, 8 and 10 are being examined.

Claims 2-3, 5, 17-18, 27-29 seem to be free of prior art and are allowable.

The following are the remaining rejections.

This application contains claims drawn to an invention nonelected with traverse in Paper of 02/03/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

INFORMATION DISCLOSURE STATEMENT

The signed copy of the PTO-1449 of 01/08/02 is enclosed therewith.

PRIORITY DATE

Applicant submits a Declaration stating that a laboratory notebook (Exhibit A) shows a sequence that is the species of the genus of the claimed nucleic acid molecules which hybridize specifically with a complete complement of SEQ ID NO:1. Applicant asserts that the date of the notebook has been redated, and the experiments were performed prior to May 22, 1998, the date of the recited art WO 98/21328-A2 in

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the 102(a) rejection. Applicant asserts that thus Applicant has possession of the nucleic acid of new claim 21.

The submission of the Declaration is acknowledged and entered.

It is noted that Exhibit A does not show any date. Further, it is not clear what kind of redate is referred to.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

New claims 20-24, 26, 35-40 are rejected under 35 USC 112, first paragraph for lack of a clear written description of a nucleic acid sequence that hybridizes specifically with nucleotides 77-1753 of SEQ ID NO:1, or with SEQ ID NO:1, and a method of detecting prostate cancer by detecting an abnormal high level of said nucleic acid sequence.

Applicant argues that it would be clear to one of skill in the art that is meant by the term "hybridizes specifically". Applicant argues the specification is replete with example of specific hybridization.

Applicant's arguments set forth in papers of 11/05/04 and 11/17/04 have been considered but are not deemed to be persuasive for the following reasons:

Since there is no definition of "hybridizes specifically" in the specification, "hybridizes specifically". Encompasses hybridizes under very low specific to very high specific conditions.

Further, even under the highest stringent conditions, the claimed hybridizing sequences encompasses sequences with unknown structure that are attached to SEQ ID NO:1 or nucleotides 77-1753 of SEQ ID NO:1, via a common fragment.

Thus the specification does not meet the written requirement, since Applicant did not have in possession at the time of filing the claimed hybridizing sequences.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Claims 10-12, 19, 20-24, 26, 35-40 are rejected under 35 USC 112, first paragraph.

1. New claims 20-24, 26, 35-40 are rejected under 35 USC 112, first paragraph, because while being enabled for SEQ ID NO:1, and a method for detecting prostate cancer, comprising detecting an increase in the mRNA level of SEQ ID NO:1 in prostate cancer tissue as compared to normal prostate tissue control, the specification lacks enablement for a nucleic acid sequence that hybridizes specifically with nucleotides 77-1753 of SEQ ID NO:1, or with SEQ ID NO:1, and a method of detecting prostate cancer by detecting an abnormal high level of said nucleic acid sequence.

Applicant argues that it would be clear to one of skill in the art that is meant by the term "hybridizes specifically". Applicant argues the specification is replete with example of specific hybridization.

Applicant's arguments set forth in papers of 11/05/04 and 11/17/04 have been considered but are not deemed to be persuasive for the following reasons:

Since there is no definition of “hybridizes specifically” in the specification, “hybridizes specifically”. Encompasses hybridizes under very low specific to very high specific conditions.

Further, even under the highest stringent conditions, the claimed hybridizing sequences encompasses sequences with unknown structure that are attached to SEQ ID NO:1 or nucleotides 77-1753 of SEQ ID NO:1, via a common fragment.

One of skill in the art does not know how to make the claimed hybridizing sequences.

2. Claims 10, 12, 19, 20, 22, 24, 30-31, 33, 36-37, 39 are rejected under 112, first paragraph, because while being enabled for a method for detecting prostate cancer, by detecting an increased level of SEQ ID NO:1 in prostate cancer tissue as compared to normal prostate tissue, the specification is not enabled for a method of detecting prostate cancer by detecting an abnormal high level of SEQ ID NO:1 in any tissue, or any fluid, including bodily fluid.

Applicant argues that the specification discloses which tissue or bodily fluid would be suitable. Applicant recites Itoh et al, Lombardo et al, and Tricoli et al, stating that markers for prostate cancer have been detected in human serum, urine, and seminal fluid.

Applicant further argues that the references cited by the Examiner do not disclose markers that are up-regulated in primary tumors, then down regulated during metastasis, and thus do not bear on the present situation. Applicant argues that the

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cited references report studies performed with cell lines, clones or transfected models, and thus may not reflect event which occur in vivo.

The recitation of Itoh et al, Lumbardo et al, and Tricoli et al is acknowledged and entered.

Applicant's arguments set forth in papers of 11/05/04 and 11/17/04 have been considered but are not deemed to be persuasive for the following reasons:

The specification discloses that samples may be a bodily fluid, including "but not limited to" blood, urine, and seminal fluid. Thus bodily fluid is not limited to blood, urine, and seminal fluid, and could be any fluid in the body, to which the prostate cancer cells have metastasized. One cannot predict however that metastasized prostate cancer cells still have SEQ ID NO:1 upregulated, in view of the teaching in the art that numerous genes change their expression during progression toward metastasis (Kibel, Zhau, Cheung and Ren, all of record)

Further, although the cited references do not disclose markers that are up-regulated in primary tumors, then down regulated during metastasis, they apply to the claimed invention as well, because from the teaching in the art, one cannot predict the expression of which gene is affected by metastasis, regardless of whether said gene was upregulated in primary prostate cancer.

Further, the cited references apply as well in vivo , because the cited references Kibel, and Cheung et al teach inactivation of numerous genes in primary cancer tissues versus metastatic tissues.

REJECTION UNDER 35 USC 102(a or b)

Claims 21, 35 are rejected under 35 USC 102(a or b) as being anticipated by Boehringer, or WO 98/21328-A2, of record.

Claims 21, 35 are drawn to a nucleic acid molecule that hybridizes specifically with SEQ ID NO:1 or nucleotides 77-1753 of SEQ ID NO:1.

The teaching of Boehringer, or WO 98/21328-A2 has been set forth in previous Office action.

In brief, Boehringer teaches all possible 6-nucleotide sequences. WO 98/21328-A2 teaches a sequence that is 99.5% similar to SEQ ID NO:1 from nucleotide 64 to nucleotide 2317. The sequence taught by the art would hybridize specifically with SEQ ID NO:1 or nucleotides 77-1753 of SEQ ID NO:1.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS
January 28, 2005

SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

